## APPENDIX

UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

October Term, 1966

Patent Appeal No. 7522

Serial No. 796,749

In the Matter of the Application of

DAVID NEVILLE KIRK AND VLADIMIR PETROW

March 16, 1967

WORLEY, Chief Judge.

This appeal is from the decision of the Board of Appeals affirming the rejection of claims 11, 25, 26, 28, 29, 39, 41 and 45 in appellants' application[1] entitled "1-Dehydro-6-Methyl Steroid Compounds."

Each claim defines a specific steroid compound, claim 11 relating to a compound of the spirostane series; claims 25, 26, 28, 29 and 45 to compounds of the androstane series; and claims 39 and 41 to compounds of the pregnane series. It is unnecessary to reproduce any claim since the nature of the compounds will become apparent.

The Patent Office rejected all claims for failure of the specification "to comply with 35 USC 101 and 112." As we view the record, we are concerned with not only the legal adequacy of appellants' disclosure of "how to use" the claimed compounds under 35 USC 112,[2] but also the legal

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[1] Serial No. 796,749, filed March 3, 1959.

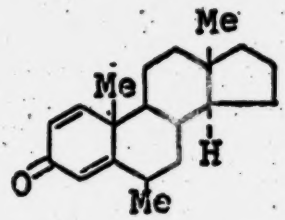
[2] 35 USC 112 reads in pertinent part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

adequacy of assertions of usefulness in the original specification under 35 USC 101.[3] We are particularly concerned with the applicability of the decision of the Supreme Court in *Brenner* v. *Manson*, 383 U.S. 519, to the facts here.[4]

The appropriate starting point for disposition of those issues is appellants' specification, which begins with several general statements as to how the claimed compounds are useful:

> It is an object of the present invention to provide a process for the conversion of 3-oxo-$\Delta^4$-6-methyl and 3-oxo-$\Delta^{4,6}$-6-methyl steroidal derivatives into the corresponding 1-dehydro-derivatives which are a new class of compounds *often possessing high biological activity.*
>
> The present invention provides new 1-dehydro-derivatives of 3-oxo-$\Delta^{4,6}$-6-methyl and certain 3-oxo-$\Delta^4$-6-methyl steroids having the formula




[3] 35 USC 101 reads in pertinent part:

> Whoever invents or discovers any new and *useful* process, machine, manufacture, or *composition of matter*, or any new and useful improvement thereof, may obtain a patent therefor, *subject to the conditions and requirements of this title.* (Emphasis supplied)

[4] This appeal was originally argued December 7, 1965, some three months prior to the decision in *Brenner* v. *Manson* on March 21, 1966. On November 10, 1966, this court restored the appeal to the calendar for reargument, and requested counsel to file memoranda "on the effect, if any, of *Brenner* v. *Manson* * * * on this appeal." Argument on that question was heard December 5, 1966.

(with or without a double bond at the 6:7 position) which 1-dehydro-derivatives are of value *on account of their biological properties* or *as intermediates in the preparation of compounds with useful biological properties* as herein indicated or as is apparent to those skilled in the art.

* * * * *

The invention also provides the following new steroidal 6-methyl-1:4-dien-3-ones and 6-methyl-1:4:6-trien-3-ones which are of value *in steroid technology, in the furtherance of steroidal research and in the application of steroidal materials* to veterinary or medical practice, whether as tablets, elixirs, injections, implants, or other types of pharmaceutical preparation well known to those skilled in the art. (Emphasis supplied)

The description continues with lists of specific compounds of the cholestane, spirostane, androstane and pregnane steroid series together with a recital of "uses" for the compounds recited in the lists. Two compounds of the spirostane series are disclosed, one of which, 6-hydroxy-6-methyl-25D-spirosta-1:4-dien-3-one, is the subject of claim 11. They are said to be

* * * of value *as intermediates in the preparation of 6-methylated aromatic steroid hormones* into which intermediates they may be converted by reaction in solution in acetic anhydride with toluene-*p*-sulphonic acid. (Emphasis supplied)

Eighteen compounds of the androstane series are disclosed. The five recited in the claims are

17$\beta$-Hydroxy-6:17$\alpha$-dimethylandrosta-1:4:6-trien-3-one [Claim 45]

17$\alpha$-Ethynyl-17$\beta$-hydroxy-6-methylandrosta-1;4:6-trien-3-one [Claim 25]

17β-Acetoxy-4:6α-dimethylandrosta-1:4-dien-3-one [Claim 26]

9α-Fluoro-11β:17β-dihydroxy-6α:17α-dimethylandrosta-1:4-dien-3-one [Claim 28]

17β-Hydroxy-6α-methyl-17α-(prop-l-ynyl) androsta-1:4-dien-3-one [Claim 29]

They are said to be

> * * * of value *as intermediates in the preparation of 6-methylated aromatic steroidal hormones,* into which they may be converted by reaction in solution in acetic anhydride with toluene-*p*-sulphonic acid, *as intermediates in the preparation of biologically active compounds and in some cases on account of their biological properties.* (Emphasis supplied)

Some sixteen compounds of the pregnane series are disclosed, including the two compounds of claims 39 and 41,

6α-Methyl-16α:17α-*iso*propylidenedioxy-pregna-1:4-diene-3:20-dione [Claim 39] and

20:20-Bisethylenedioxy-6α-methylpregna-1:4-dien-3-one [Claim 41].

They are alleged to be

> * * * of value *as intermediates in the preparation of compounds with valuable biological properties such as progestational properties or properties associated with the adrenocortical hormones or as intermediates in the preparation of compounds with useful biological properties.* (Emphasis supplied)

Appellants' arguments are, in the main, two-fold. They first contend that the specification is adequate to comply with § 101 and § 112 because it discloses that the claimed compounds "have present and useful biological activity of

the nature known for analogous steroidal compounds," and that "one skilled in the art would know how to use the compounds of the claims to take advantage of their presently-existing biological activity." The second argument is that the specification adequately discloses that the compounds "have use as intermediates in the production of aromatic steroidal hormones and other biologically useful compounds," and that the examiner has admitted one skilled in the art would know how to use the claimed compounds as intermediates for that purpose. The respective arguments present somewhat different considerations, and will be discussed separately.

I. *The Asserted "Therapeutic" or "Biological" Activity*

In his final rejection, the examiner stated:

> All the claims are again rejected as lacking adequate utility. The disclosure fails to indicate to one skilled in the art how one is to use the novel compounds of this invention. The therapeutic properties are stated in such general terms i.e., "useful biological properties", that it fails to convey any useful information to one skilled in the art and further fails to state which of the claimed compounds have a therapeutic activity. * * *

In response, appellants submitted arguments that the rejection "is not warranted," and also submitted an affidavit of one of the applicants, a Dr. Petrow, which appellants summarized in a letter accompanying the affidavit and substantially reiterate in their brief here:

> Attached hereto is an affirmation of Vladimir Petrow which shows that one skilled in the art would be able to determine the biological uses of the claimed compounds by routine tests. The Petrow affirmation specifically shows that * * * [the steroid of] (Claim 25) in the well-known McPhail modification of the Clauberg

Assay possesses progestational activity on oral administration. The natural hormone, progesterone, on the other hand shows no response on oral administration in the same test. Accordingly, it is quite evident that the compound of claim 25 is a valuable oral progestational agent. This affirmation, accordingly, is proof of the fact that one skilled in the art would have no difficulty in determining whether *or not* the 1-dehydro derivatives of the pregnane series, as claimed, have value biologically as progestational agents. (Emphasis supplied)

In addition, the Petrow affirmation * * * discloses the determination of the anabolic activity of * * * the compound of claim 26. It is shown by standard test procedure that this compound does have anabolic activity and that, in addition, it has a much higher anabolic/androgenic ratio than that of testosterone propionate, a well-known anabolic agent. * * *

Further * * * the oral progestational activity of * * * the compound of claim 39, is set forth by virtue of *well-known test procedure.* This pregnane derivative is shown to be approximately 4 times as active progestationally on oral administration as * * * a well-known oral progestational agent. * * * by means of other tests the compound of claim 39 has been found to have valuable anti-inflammatory activity greater than that of either cortisone acetate or hydrocortisone. By virtue of a further standard test procedure the gluco corticoid activity of the compound of claim 39 has been shown to be more than 10 times that of cortisone and hydrocortisone acetates.

The affirmation of Dr. Petrow not only shows that the compounds claimed do have biological activity as asserted in the specification, but that the nature of such biological activity can be readily determined by

those skilled in the art by reason of standard test procedures.[5]

Appellants' affidavit and argument went for naught, the examiner responding that

> * * * the final rejection of all the claims in the case as lacking an adequate disclosure of utility is deemed sound and adhered to. * * *

In his Answer before the board, the examiner rejected the claims

> * * * as failing to comply with 35 U.S.C. 101 and 112 in that the specification fails to teach those skilled in the art how to use the invention. * * *

After reviewing the various passages of appellants' specification relating to the uses of the claimed compounds and "how to use" them, he concluded:

> * * * nowhere is there found a *specific* allegation of utility for any compound within the scope of the claims. Thus the specification does not describe the manner in such full, clear, concise and exact terms as to enable one skilled in the steroid art to use the compounds of the instant invention. * * * Appellants have not listed one specific use for their claimed steroids and as those skilled in the art know steriods are susceptible to hundreds of uses. *What appellants are really saying to those in the art is take these steroids, experiment, and find what use they do have as medicines.* (Emphasis supplied)

With regard to the Petrow affidavit, the examiner stated:

> * * * it may be that oral progestational activity can be determined by procedures well known in the art.

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[5] The record shows that the "standard test procedures" involved the use of laboratory animals, specifically rats and rabbits.

> * * * Once one knows that a compound does have utility as a progestational agent, it is of course merely routine to determine at what doses this activity exists. In other words, if in the specification as filed there had been a specific allegation that the compounds herein claimed had progestational activity this would have been sufficient to satisfy 35 U.S.C. 112, since those skilled in the art would know how to use a steroid possessing progestational activity. Thus, the aforementioned affidavit is not determinative of the issue at bar which is if the specification as filed does not allege a specific utility would one skilled in the art know how to use the invention?

The board agreed, adding that the reference in the specification to "biological properties" of the claimed compounds "is so general and vague as to be meaningless." It found in the specification no reason to expect that any of the claimed compounds "presents the probability of usefulness in the same manner as a natural hormone."

Appellants rely on the allegations in their specification that the disclosed compounds have "biological activity" as adequate disclosure of a use for the claimed compounds, stating:

> The disclosure teaches that the novel compounds are, in some cases, of value because of their presently existing biological activity. The application * * * teaches that such *steroidal* materials may be applied to veterinary or medical practice in the form of tablets, elixirs, injections, implants or other pharmaceutical preparations. In other words, the compounds in question are to be used *in the manner of other steroid hormones* in veterinary or medical compositions.

They also rely on the Petrow affidavit as evidence of the proposition that one skilled in the art would know how to use the claimed compounds, and assert that "the Board

erroneously, completely ignored the Petrow affirmation confirming present useful hormonal activity of some of the compounds * * *."

We are not persuaded by appellants' arguments that their specification meets the requirements of §§ 101 and 112. It seems to us that the nebulous expressions "biological activity" or "biological properties" appearing in the specification convey no more explicit indicatfon of the usefulness of the compounds and how to use them than did the equally obscure expression "useful for technical and pharmaceutical purposes" unsuccessfully relied upon by the appellant in *In re Diedrich*, 50 CCPA 1355, 318 F.2d 946, 138 USPQ 128.[6]

Nor does the Petrow affidavit help appellants' cause here. While that affidavit may show that three of appellants' claimed compounds do *in fact* possess specific anabolic, anti-inflammatory or glucocorticoid activity or usefulness as oral progestational agents, that is not the issue before us. It is what the compounds are *disclosed* to do that is determinative here. In that regard, it is appropriate to note that the specification does not even intimate that the claimed compounds of the spirostane and pregnane series *themselves* have "biological activity," much less the specific progestational, glucocorticoid or anti-inflammatory activities mentioned in the affidavit. With respect to the eighteen androstanes that are disclosed, five of which are claimed here, it is said they "are of value * * * *in some cases* on account of their biological properties." (Emphasis supplied.) There is no suggestion

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[6] There this court affirmed the rejection of certain claims for failure of an application to comply with section 112, noting that it had no "*specific* disclosure as to just *how* the compounds are to be *used*."

*which* androstanes are of value for that reason, or *what* biological properties make them useful.[7]

Thus we agree with the solicitor that appellants' affidavit is simply an *ex post facto* affirmation irrelevant to the issue of adequacy of the original disclosure inasmuch as it attempts to add statements of usefulness to the disclosure of the application as filed. Indeed, the sum and substance of the affidavit appears to be that one of ordinary skill in the art would know "how to use" the compounds to find out in the first instance whether the compounds *are—or are not—in fact* useful or possess useful properties, and to ascertain what those properties are. It amounts to an admission that experimentation would be necessary to determine actual uses—or possible lack of uses—of the compounds, as well as how to employ them in a useful manner. But surely Congress intended § 112 to presuppose *full satisfaction* of the requirements of § 101. Necessarily, compliance with § 112 requires a description of how to use presently useful inventions, otherwise an applicant

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[7] Appellants also rely on this court's decision in *In re Hitchings*, 52 CCPA 1141, 342 F.2d 80, 144 USPQ 637; *In re Dodson*, 48 CCPA 1125, 292 F.2d 943, 130 USPQ 224; *In re Krimmel*, 48 CCPA 1116, 292 F.2d 948, 130 USPQ 215; and *In re Bergel*, 48 CCPA 1102, 292 F.2d 955, 130 USPQ 206, for the proposition that usefulness of compositions of matter under § 101 may be established by an appropriate demonstration that the composition has useful properties or activities when tested in laboratory animals. Appellants correctly point out that the Supreme Court in *Brenner* v. *Manson* neither approved nor disapproved the reasoning and conclusions of those cases, 383 U.S. 531. However, appellants' reliance on those cases here appears misplaced. In those cases, the inventors had carried their invention substantially further than appellants here, pharmacological testing having proceeded to an extent that some particular salutary effects on conditions inimical to animals could be ascribed to the compounds in issue there. The general results of those tests were disclosed in the application as filed, in contrast to the situation here. See also *Archer* v. *Papa*, 46 CCPA 835, 265 F.2d 954, 121 USPQ 413; *Blicke* v. *Treves*, 44 CCPA 753, 241 F.2d 718, 112 USPQ 472.

would anomalously be required to teach how to use a useless invention. As this court stated in *Diedrich*, quoting with approval from the decision of the board:

> We do not believe that it was the intention of the statute to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.

As the Supreme Court said in *Brenner* v. *Manson*:

> * * * a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. * * *

Appellants further argue that the board had no grounds for concluding there was "no definite expectation from the specification" that any one of the claimed compounds "presents the probability of usefulness in the same manner as a natural hormone." According to appellants, "The analogy to known natural and synthetic hormones [presumably appellants intend to draw an analogy in chemical make-up or constitution between the claimed compounds and, for example, the natural hormone progesterone] enables one to predict that the new compounds would possess similar hormonal activity." Moreover, since some of the disclosed compounds of the pregnane series, not claimed here, were stated in the specification to be of value on account of their hydrocortisone-like anti-inflammatory properties, appellants contend that "it would not be unreason-

able to predict that others of this series [i.e. the claimed pregnane derivatives] would also have this property."

Similar arguments were advanced before, and rejected by, the Supreme Court in *Brenner* v. *Manson,* 383 U.S. at 531-2. We find no error in the board's position on the facts of this case, absent a disclosure in the specification that the requisite properties of the *claimed* compounds are also similar to those of a natural or synthetic hormone of known activity. Appellants' arguments fail to recognize that many steroid compounds may possess no activity whatsoever. It cannot be presumed that a *steroid* chemical compound is "useful" under § 101, or that one of skill in the art will know "how to use" it, simply because the compound is closely related only in a structural sense to other steroid compounds known to be useful. Cf. *In re Adams,* 50 CCPA 1185, 316 F.2d 476, 137 USPQ 333, dissenting opinion.

We conclude that appellants' specification does not comply with § 101 and § 112 merely on the statements of "biological" activity recited therein.

II. *The Asserted Usefulness as an "Intermediate"*

As can be seen from the portions of the specification quoted earlier, appellants disclose that the claimed spirostane and androstane derivatives may be used as intermediates in the formation of 6-methyl aromatic steroids, and that the claimed pregnane derivatives may similarly be employed to produce steroids having "progestational properties" or "properties associated with the adrenocortical hormones."[8]

[8] The disclosure with respect to the claimed pregnanes was characterized by the board as "even less helpful as to the manner in which these compounds may be used." We note, as did the solicitor that appellants do not *disclose* either broadly or specifically what steroids having "progestational" or "adreno-cortical" properties may be produced from the claimed pregnanes. There is no hint

The examiner has conceded that "those skilled in the art would know how to produce aromatic steroids" from the claimed compounds. However, he did not believe the inquiry into the adequacy of the disclosure should stop there, noting:

> * * * As to the portions of the disclosure which indicates that the claimed compounds are useful as intermediates in the production of 6-methylated aromatic steroids, *applicants have failed to show even one useful aromatic steroid which corresponds to the claimed intermediates. In other words, applicants' statement of utility is to the effect that the novel compounds claimed herein are useful in making other novel compounds which have no known use.* In the Examiner's opinion this is not sufficient nor does the Examiner know of any decision holding that such a statement is adequate. (Emphasis supplied)

Appellants contend that the examiner's holding[9] "is straight into the teeth" of the decision of this court in

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in the disclosure as to what additional molecular substituents, if any, must be present in the steroids to be produced from the claimed pregnanes to obtain the recited properties. Nor do appellants direct our attention to *any* specific compound, possessing some specific property and known to the art at the time they filed their application, which can be prepared from the claimed pregnanes.

[9] It is interesting to compare the rejections voiced by the examiner and board and summarized by the solicitor in *Nelson*, 47 CCPA 1037-9, 280 F.2d 176-7, 126 USPQ 247, with those raised here. For all intents and purposes, the rejections are identical. Although the board here found no decision "more directly relevant" than *Nelson*, nevertheless the examiner, board nd solicitor all seek to distinguish it, urging that this court "evidently felt" that at least some of the products which could be made using Nelson's compounds as intermediates would be final products usable with no experimentation for specific therapeutic end purposes. The court did not intend *Nelson* to have the narrow scope attributed to it by the Patent Office. The most the court knew about what could be done with Nelson's C-19 14-hydroxy androstenes was that

*In re Nelson,* 47 CCPA 1031, 280 F.2d 172, 126 USPQ 242. They urge that the present disclosure with respect to the usefulness of the claimed compounds as intermediates "is on all fours" with that in *Nelson.* In their view, the examiner's requirement for disclosure of a use of the final products produced by carrying out the known process on the novel intermediates of the claims "is an absurdity" in view of *Nelson* and the further decisions of this court in *In re Wilke,* 50 CCPA 964, 314 F.2d 558, 136 USPQ 435; *In re Adams;* and *In re Manson,* 52 CCPA 739, 333 F.2d 234, 142 USPQ 35. They look upon the latter decisions as carrying forward the principle expressed in *Nelson* that, in their words, "there is no necessity for a specification to teach the use of an end product where such end product is not the invention claimed, but merely the result thereof."

The decision in *Nelson* might well control here—*if* that decision were still a viable precedent. The question re-

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they could be used as intermediates to produce "steroids of a class at least some members of which are known to have useful therapeutic properties." The court took that as no guarantee that any of the *particular* "final products" which might be produced from Nelson's *particular* intermediates themselves would have the cardiac glycoside activity of other members of the class. As appellants correctly note in their brief:

> In the *Nelson* case, one skilled in the art could not exactly predict what therapeutic properties the end products produced by the use of the claimed intermediates might have, nor could they predict that they would possess any at all. * * *

Appellants, however, also urge that their intermediates are "useful" substances even under the Patent Office interpretation of *Nelson.* They contend that the 6-methyl aromatic steroids produced from their claimed compounds *are* members of a class of aromatic estrogen compounds, some of which are useful commercially. They refer specifically to certain members of that class in their brief. But appellants have not disclosed or otherwise shown that *any* 6-methyl aromatic steroid which can be produced from their intermediates possesses activities in common with those commercial members of the aromatic steroid series. We cannot accept their arguments for reasons given under Part I of this opinion.

mains, however, whether the majority view in *Nelson*—that steroid chemical compounds may be useful under § 101 if they are useful to chemists doing research on steroids and can be used to produce steroids which are members of a general class some members of which are known to have useful therapeutic properties—can possibly remain the law in view of *Brenner* v. *Manson*.

There the Supreme Court, in considering what renders a process useful under § 101, discussed the cases cited by appellants here, stating (all emphasis supplied):

> As is so often the case, however, a simple, everyday word [useful] can be pregnant with ambiguity when applied to the facts of life. That this is so is demonstrated by the *present conflict between the Patent Office and the CCPA* over how the test is to be applied to a chemical process which yields an already known product whose utility—*other than as a possible object of scientific inquiry*—has not yet been evidenced. It was not long ago that agency and court seemed of one mind on the question. In *Application of Bremner*, 37 C.C.P.A. (Pat.) 1032, 1034, 182 F.2d 216, 217, the court affirmed rejection by the Patent Office of both process and product claims. It noted that "no use for the products claimed to be developed by the processes had been shown in the specification." It held that "It was never intended that a patent be granted upon a product, or a process producing a product, unless such product be useful." Nor was this new doctrine in the court. See *Thomas* v. *Michael*, 35 C.C.P.A. (Pat.) 1036, 1038-1039, 166 F.2d 944, 946-947.
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> The Patent Office has remained steadfast in this view. The CCPA, however, has moved sharply away from *Bremner*. The trend began in *Application of Nelson*, 47 C.C.P.A. (Pat.) 1031, 280 F.2d 172. There, the court reversed the Patent Office's rejection of a claim on a process [product] yielding chemical intermediates

"useful to chemists doing research on steroids," *despite the absence of evidence that any of the steroids thus ultimately produced were themselves "useful."* The *trend has accelerated,*[10] *culminating in* the present case where the court held it sufficient that a process produces the result intended and is not "detrimental to the public interest." 52 C.C.P.A. (Pat.) at 745, 333 F.2d at 238.

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[10] In a footnote to the above comments, the Court added:

> Thus,, in *Application of Wilke,* 50 C.C.P.A. (Pat.) 964, 314 F.2d 558, the court reversed a Patent Office denial of a process claim, holding that 35 U.S.C. § 112 (1964 ed.) was satisfied even though the specification recited only the manner in which the process was to be used and not any use for the products thereby yielded. See also *Application of Adams,* 50 C.C.P.A. (Pat.) 1185, 316 F.2d 476.
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> In *Application of Szwarc,* 50 C.C.P.A. (Pat.) 1571, 319 F.2d 277, the *court acknowledged* that *its view of the law respecting utility of chemical processes had changed since Bremner.* * * * (Emphasis supplied)

Stripped of the highly technical procedural differences, the basic issue here, as in *Brenner* v. *Manson,* is whether the burden resting on an applicant to show that his invention is useful within the requirements of § 101 has been satisfied. While Manson did not disclose any use at all for the steroid compounds produced by his process, the arguments he advanced as to why those compounds were useful under § 101 correspond in substantial measure to the disclosure of the specification and the arguments relied on here. There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of "useful in research" or "useful as building blocks of value to the researcher" was recognized, and clearly rejected, by the Supreme Court:

> Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, *we believe*

*a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility,* creates a monopoly of knowledge which should be granted *only* if clearly commanded by the statute. * * * The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

*These arguments* for and against the patentability of a *process* which either *has no known use* or is *useful only in the sense that it may be an object of scientific research* would *apply equally* to the patenting of the *product produced by the process.* Respondent appears to concede that with respect to a product, as opposed to a process, Congress has struck the balance on the side of nonpatentability unless "utility" is shown. Indeed, the decisions of the CCPA are in accord with the view that a product may not be patented absent a showing of utility greater than any adduced in the present case. *We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing,* a different set of rules was meant to apply to the process which yielded the unpatentable product. *That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself.* (Emphasis supplied)

Wholly aside from the controlling impact of that reasoning here, the conclusion is inescapable that, just as the

practical utility of the compound produced by a chemical process "is an essential element" in establishing patentability of the process, 383 U.S. 519, so the practical utility of the compound, or compounds, produced from a chemical "intermediate," the "starting material" in such a process, is an essential element in establishing patentability of that intermediate. It seems clear that, if a process for producing a product of only conjectural use is not itself "useful" within § 101, it cannot be said that the starting materials for such a process—i.e., the presently claimed intermediates —are "useful." It is not enough that the specification disclose that the intermediate exists and that it "works," reacts, or can be used to produce some intended product of no known use. Nor is it enough that the product disclosed to be obtained from the intermediate belongs to some class of compounds which now is, or in the future might be, the subject of research to determine some specific use.[11] Cf. *Reiners* v. *Mehltretter*, 43 CCPA 1019, 1026, 236 F.2d 418, 421, 111 USPQ 97, 100, where compounds employed as intermediates to produce other *directly* useful compounds were found to be themselves useful.

It is impossible to reconcile the reasoning and conclusion of the majority in *Nelson, Wilke, Adams* and *Szwarc* with the majority view in *Brenner* v. *Manson*. Therefore, to the extent that those decisions are inconsistent with *Brenner* v. *Manson* and the views expressed herein, they must be, and are, overruled.

The decision is *affirmed*.

AFFIRMED.

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[11] It does not appear that appellants seriously disagree with us on the matter, for in their memorandum on reargument they state:

> C. By analogy between a process for production of a product and an intermediate for producing an end product, such intermediate would not be useful within the meaning of 35 U.S.C. 101 merely because it can be used to make the intended product, or because the end product belongs to a class of compounds now the subject of serious scientific investigation.

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March 16, 1967

RICH, Judge.

**Notice of Forthcoming Dissenting Opinion**

I, like Judge Smith, whose sentiments I share, am now revising a dissenting opinion to cover this case and the companion *Joly* case (No. 7472), argued together December 5, 1966, and involving similar issues. I initially filed my tentative dissenting opinion herein February 1 in response to the December 22 majority opinion and a January 24 opinion in *Joly*. Thereafter the majority opinion in *Joly* was 75% rewritten on February 8 and again, on February 20, its content, responsive in part to observations in my dissent, was reduced 50%. In the ensuing three weeks the court has conferred on a long agenda of cases and held a week of hearings March 6-10, upon the conclusion of which I resumed, on March 13, my revision of the dissent. On that day notice was given by the Chief Judge that these two cases "will go down Thursday, March 16."

Protest to the arbitrary use of assumed power having proved futile, this unprecedented display of unseemly haste, condoned by the majority, necessitates this notice.

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March 16, 1967

SMITH, Judge, dissenting.

Our usual practice is to release the majority opinion simultaneously with any dissenting opinions. There has been an unwarranted departure from this procedure in this case, the effect of which is to preclude an expression of my views at this time. I am unable to see wherein the cause of justice is served by such an irregular procedure. This dissent is therefore 1) a protest to the procedure here adopted, and 2) a notice that my full written dissent will be forthcoming as soon as the pressures of court work permit.

UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

October Term, 1966

Patent Appeal No. 7522

Serial No. 796,749

IN THE MATTER OF THE APPLICATION

OF

DAVID NEVILLE KIRK AND VLADIMIR PETROW

March 16, 1967

WORLEY, Chief Judge, specially concurring.

It is most regrettable that for the first time in the history of this court, the usual orderly processes of the court have been ignored by a minority.

The instant appeal was *re-argued* December 5, 1966. The majority opinion was circulated December 22 in its present form. Yet, now, nearly three months later, the dissenting opinions are not available and no valid excuse is given.

It would seem that if the majority can direct its time and attention to expediting the work of the court it should not be too much to expect the same diligence from the minority.

It should not be necessary to say that the duty of this court is to the litigants, applicants for patents, the Patent Office and the public—not to the possible whims and caprices of individual judges. It is impossible to discharge that duty by condoning the instant derelictions, which hereafter will not be countenanced.

UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

October Term, 1966

Patent Appeal No. 7472

Serial No. 81,272

IN THE MATTER OF THE APPLICATION
OF
ROBERT JOLY AND JULIEN WARNANT

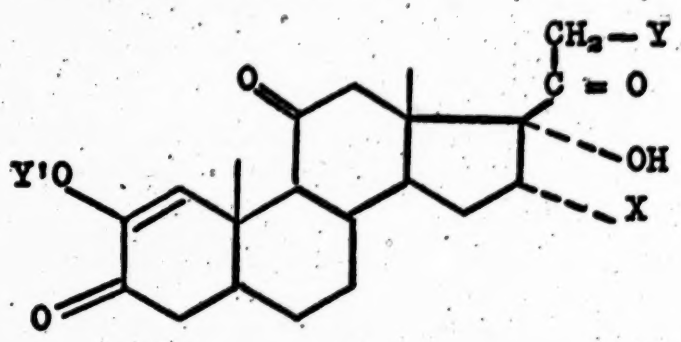
March 16, 1967

ALMOND, Judge.

This is an appeal from the decision of the Board of Appeals affirming the rejection of product claims 1 to 3 and process claims 8 to 12 of appellants' application serial No. 81,272, filed January 9, 1961, entitled "Esters of 2-Enols of $\Delta^1$ Steroids and Preparation Thereof."

Generic product claim 1 is illustrative:

1. A compound having the formula




wherein X is selected from the group consisting of hydrogen and methyl, Y is selected from the group consisting of hydrogen and an acyloxy radical of a lower organic carboxylic acid having 1 to 7 carbon atoms and Y' is an acyl radical of a lower organic carboxylic acid having 1 to 7 carbon atoms.

Composition of matter claims 2 and 3 are directed to specific compounds, 2,21-diacetoxy-$\Delta^1$-pregnene-17$\alpha$-ol-3,11,20-trione and 2-acetoxy-16$\alpha$-methyl-$\Delta^1$-pregnene-17$\alpha$-ol-3,11,20-trione, respectively. Claims 8 to 12 are directed to a process for the manufacture of the claimed steroids, which appellants disclose in their specification to be "useful as intermediates" in the following terms:

> The products obtained by the invention, the lower organic carboxylic acid esters of enols in the 2-position of $\Delta^1$-steroids, are particularly useful as intermediates in the preparation of steroids, especially steroids having a ketone group in the 2-position, such as 21-acetoxy-pregnane-17$\alpha$-ol-2,3,11,20-tetraone and 16$\alpha$-methyl-pregnane-17$\alpha$-ol-2,3,11,20-tetraone by acid hydrolysis and customary separation steps.

The Board of Appeals rejected all claims for appellants' failure to satisfy the requirements of 35 USC 101 and 112. Here, as in *In re Kirk*, 54 CCPA , F.2d , USPQ , decided concurrently, we are primarily concerned with the adequacy in law of the aforementioned assertions of usefulness in appellants' original application. Here, too, we are particularly concerned with the applicability of the decision of the Supreme Court in *Brenner* v. *Manson*, 383 U.S. 519, 148 USPQ 689, to the present facts.[1]

In their memorandum on reargument, appellants concede that, in view of *Brenner* v. *Manson*, the appealed process claims should not be found allowable unless we find the claimed compounds produced by that process to

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[1] This appeal was originally argued October 8, 1965, some five months prior to the decision in *Brenner* v. *Manson* on March 21, 1966. On November 10, 1966, this court restored the appeal to the calendar for reargument, and requested counsel to file memoranda "on the effect, if any, of *Brenner* v. *Manson* * * * on this appeal." Argument on that question was heard December 5, 1966.

be "useful" under section 101. It is to that issue that we direct our attention.

The examiner finally rejected all claims for "insufficient disclosure of utility." Analyzing the above disclosure in appellants' specification, he stated:

> * * * the applicants have stated only that the [claimed] final products may be converted to the corresponding 2-keto compounds, *which compounds have no known utility.* * * * [Emphasis supplied.]

The board agreed, adding:

> The portion of the specification * * * show that the claimed compounds can be used to prepare the corresponding 2,3-keto compounds. *Having arrived at that point, what has been accomplished?* Appellants do not assert that the latter compounds have known utility * * *.
>
> * * * * *
>
> * * * such conversion does not constitute a disclosure of utility for the claimed compounds because there is no disclosed utility nor any indication of a known utility for the 2,3-keto derivatives. *A useless product does not become useful by virtue of conversion into another useless product.* [Emphasis supplied.]

Appellants do not contend that a use for the claimed compounds, other than as starting materials or intermediates in a process of making other compounds, was either known or obvious to one of ordinary skill in the art at the time their application was filed. Rather, they urge that the claimed esters are "useful as intermediates" in the preparation of certain 2,3-diketo steroids. Although appellants admit that "no specific utility is stated" for the

two named 2,3-diketo steroids[2] which can be produced from the compounds of claims 2 and 3, they contend that those diketo compounds are "closely related" in chemical structure to compounds of known usefulness, viz, cortisone and prednisone. Appellants argue that "[t]he disclosure of a steroid as useful as an intermediate to make other steroids by specific disclosed reactions is an adequate disclosure of utility."

We do not accept those arguments. There is no evidence of record that the particular 2,3-diketo steroids which can be obtained from the claimed compounds possess *properties* or *activities* in common with the allegedly "closely related" compounds having known useful properties, cortisone and prednisone. Similar arguments were presented to, and rejected by, the Supreme Court in *Brenner* v. *Manson,* 383 U.S. at 531-2, and this court in *In re Kirk* where we stated:

> It cannot be presumed that a *steroid* chemical compound is "useful" under § 101, or that one of skill in

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[2] In a letter dated April 6, 1962, appellants urged before the Patent Office that the 2,3-diketo steroids in turn "are known to be useful in the formation of A-nor steroids." Insofar as the record shows, no evidence or argument was presented at that time or any other time in the proceedings below that any "A-nor steroid" which might ultimately be produced from the claimed compounds would itself be a useful product, the board noting:

> * * * there is nothing to indicate that the derivative dicarboxylic acid compounds or the ultimate A-nor compounds have any utility. * * *

Appellants argue here that the particular 2,3-diketo steroid which is prepared from the compound of claim 2 can itself be used to prepare a compound of "recognized therapeutic activity," A-nor cortisone. They rely on certain documentary material in their brief, not part of the evidence before the Patent Office, to support the proposition that A-nor cortisone, known to be useful at the time of filing their application, can be prepared from the claimed compounds. We have not considered that "evidence." See *In re Cofer,* 53 CCPA 830, 354 F. 2d 664, 148 USPQ 268.

> the art will know "how to use" it, simply because the compound is closely related only in a structural sense to other steroid compounds known to be useful.
> * * *

Nor do we agree that the mere disclosure that a claimed chemical compound may be used as an intermediate to make other compounds, *without regard* for the usefulness of the latter compounds, is adequate under section 101. As we stated in *In re Kirk:*

> * * * the conclusion is inescapable that, just as the practical utility of the compound produced by a chemical process "is an essential element" in establishing patentability of the process, [*Brenner* v. *Manson*] 383 U.S. 519, so the practical utility of the compound, or compounds, produced from a chemical "intermediate," the "starting material" in such a process, is an essential element in establishing patentability of that intermediate. It seems clear that, if a process for producing a product of only conjectural use is not itself "useful" within § 101, it cannot be said that the starting materials for such a process—i.e., the presently claimed intermediates—are "useful." It is not enough that the specification disclose that the intermediate exists and that it "works," reacts, or can be used to produce some intended product of no known use. Nor is it enough that the product disclosed to be obtained from the intermediate belongs to some class of compounds which now is, or in the future might be, the subject of research to determine some specific use. * * *

We conclude that appellants have not discharged their burden to show that the claimed subject matter is "useful" within the requirements of section 101.

The decision is *affirmed.*

AFFIRMED.

UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

October Term, 1966.

Patent Appeal No. 7472.

Serial No. 81,272.

IN THE MATTER OF THE APPLICATION

OF

ROBERT JOLY AND JULIEN WARNANT

March 16, 1967

RICH, Judge.

**Notice of Forthcoming Dissenting Opinion**

I, like Judge Smith, whose sentiments I share, am now revising a dissenting opinion to cover this case and the companion Kirk case (No. 7522), argued together December 5, 1966, and involving similar issues. I initially filed my tentative dissenting opinion in *Kirk* February 1 in response to a December 22 majority opinion therein and a January 24 opinion herein. Thereafter the majority opinion herein was 75% rewritten on February 8 and again, on February 20, its content, responsive in part to observations in my dissent, was reduced 50%. In the ensuing three weeks the court has conferred on a long agenda of cases and held a week of hearings March 6-10, upon the conclusion of which I resumed, on March 13, my revision of the dissent. On that day notice was given by the Chief Judge that these two cases "will go down Thursday, March 16."

Protest to the arbitrary use of assumed power having proved futile, this unprecedented display of unseemly haste, condoned by the majority, necessitates this notice.

UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

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